

DUPLOSPRAY Preparation Instructions

Instructions for Circulating Nurse | DUPLOSPRAY MIS Regulator



1 Position DUPLOSPRAY System so the foot pedal is placed next to the surgeon's foot at time of application.



2 Adjust CO₂ source pressure to 100 psi / 7 bar (+/-5). The pressure gauge on faceplate of Regulator should indicate 18-22 psi/1.24 - 1.5 bar or in green zone.



3 Attach spray set to regulator. Connect the blue vent line filter to the blue female luer and the clear gas line filter to the clear male luer on the regulator.



4 While depressing foot pedal, adjust gas flow rate to 1.0-2.0 liters per minute. Check gas flow by noting height of ball in flow gauge while stepping on foot pedal.

Instructions for Scrub Nurse | DUPLOSPRAY MIS Applicator



1 Prepare COSEAL Surgical Sealant according to the instructions in the package insert.



2 Attach the spray head to the hubs of the syringes, ensuring the clips lock on both sides.



3 Attach gas supply line (clear luer connector) to sterile applicator. Turn white locking collar to secure connection.



4 Pass assembled syringe and spray applicator to surgeon for spray application. Attach patient vent line (red luer connector) to available female luer on trocar vent valve.



5 Ensure vent valve is fully open.

◀ TIPS FOR SCRUB NURSE

- ✓ The patient vent line attached to the trocar cannula vent valve will only vent gas out when foot pedal is depressed.
- ✓ The twin-tube assembly can be easily separated as necessary to allow freedom of movement.

Instructions for Surgeon



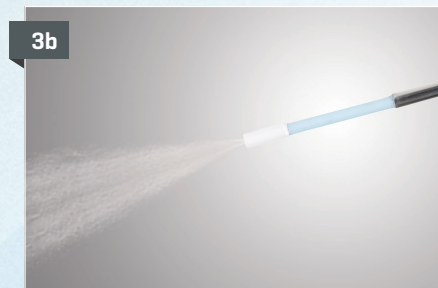
1 Press the foot pedal of the DUPLOSPRAY MIS Regulator to start the gas flow prior to applying COSEAL Surgical Sealant.



2 Check the gas flow gauge on the regulator before inserting applicator into trocar. If flow level ball does not move when foot pedal is pressed, the applicator is clogged and should be replaced.
Maximum flow rate: 2.0L/min. **Recommended spray distance: 3 cm (range 2-5 cm)**



3a While activating foot pedal dispense COSEAL Surgical Sealant by depressing syringe plungers using very slow, steady pressure.



3b To stop spray delivery release pressure on plungers while maintaining gas flow by holding down foot pedal for an additional 3-5 seconds to clear applicator.

◀ TIP FOR SURGEON

- ✓ The flexible tip at the end of the DUPLOSPRAY applicator can be angled by grasping and turning with an endoscopic grasper.



Coseal is indicated for:

- Sealing suture lines along arterial and venous reconstructions.
- Enforcement of suture and staple lines in lung resection procedures.
- Patients undergoing cardiac surgery to prevent or reduce the incidence, severity and extent of post surgical adhesion formation.
- Patients undergoing laparotomy or laparoscopic abdomino-pelvic surgery as an adjunct to good surgical technique intended to reduce the incidence, severity and extent of post surgical adhesion formation.

CONTRAINDICATIONS

- Do not use Coseal as a bronchial stump sealant, during bronchial sleeve resections, or for sealing decorticated lung areas.
- Do not use Coseal in procedures in which pleural adhesions are desired.

WARNINGS

- Application involving the use of pressurized gas may be associated with potential risks of air embolism, tissue rupture, or gas entrapment with compression, that may be life-threatening. To minimize these risks control the maximum pressure as indicated in the applicator instructions for use.
- Do not inject Coseal into vessels.
- Do not use in place of sutures, staples or mechanical closure.
- To prevent any compressive effects, in compression-sensitive cavities or in patients with an increased risk of compression (e.g. neonatal cardiac procedures), application of a thin layer of product is recommended (1 mL per 10 cm²).
- Do not use Coseal in contaminated or “dirty” pulmonary resection cases.
- Coseal swells up to four times its volume within 24 hours of application and additional swelling occurs as the gel resorbs. Therefore, surgeons should consider the maximum swell volume and its possible effect on surrounding anatomic structures potentially sensitive to compression.

For safe and proper use of this device, please refer to full device Instructions for Use.

ITEM NUMBER	PRODUCT DESCRIPTION
934073	COSEAL Surgical Sealant, 2 mL
934074	COSEAL Surgical Sealant, 4 mL
934075	COSEAL Surgical Sealant, 8 mL
0600123	DUPLOSPRAY MIS Pressure Regulator
0600043	COSEAL DUPLOSPRAY MIS Applicator 20 cm, 5 pack
0600044	COSEAL DUPLOSPRAY MIS Applicator 30cm, 5 pack

For questions or ordering information, please contact your Baxter representative

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PRECAUTIONS

- To apply Coseal for adhesion prevention, use the Coseal Spray Set or other Coseal-compatible spray device. Hold the spray set 5-10 cm from the site to provide a uniform layer to the treatment site.
- Always apply a thin, continuous layer of Coseal on large surfaces or in compression-sensitive areas using spray application. The application of excess product can be avoided by applying a minimal amount of Coseal to achieve proper sealing. A thin layer can be achieved by spraying a thickness of approximately 1 mm of product (1 mL per 10 cm²).
- DUPLOSPRAY Regulator Important Risk Information**
- Connect to regulated CO2 gas source only; maximum input pressure not to exceed 100 psi. To avoid possible gas embolism, do not directly spray into circulatory pathways. Any application of pressurized gas may be associated with a potential risk of gas embolus, tissue rupture or gas entrapment with compression, which may be life threatening. Be sure to take appropriate measures to address these risks by observing the recommended minimum sprayiing distance of 2cm (optimal working distance 3cm) and the maximal flow rate of 2.0 standard liters per minute.

